#### **REMARKS**

#### Claim Status

Claims 1-47 are pending in this application. Claims 1-47 have been rejected.

Reconsideration of the application in view of the following remarks is respectfully requested.

### Claim Amendments

Claims 16 and 25 have been amended to correct grammatical errors by adding a period at the end of the claims.

Claim 36 is amended to require that the baked product "does not comprise spray-dried calcium citrate crystals" Support for new claim 48 is found throughout the application as filed and in particular at page 6.

#### **Arguments**

## U.S. Patent No. 6,228,161 ("Drummond")

Claims 1 and 8 are rejected under § 103 as obvious over U.S. Patent No. 6,228,161 ("Drummond"). Specifically, the Examiner states that Drummond "discloses a calcium carbonate stabilized acid slurry, which has a pH of less than 6 containing water, calcium carbonate, and a weak acid." The Examiner correctly observes that Drummond does not disclose the "particular ratio of calcium carbonate to acid" recited in Applicants' claims, but argues that "the reference discloses that enough calcium compound is used to make a pH of less than 7, even though 6 is preferred" and therefore "it would have been obvious to make a product at within the claimed ratio to make a pH of about 6.5."

Applicants respectfully submit that the rejection over Drummond is improper because Drummond is nonanalogous art. In order to rely on a reference outside of the field of endeavor to which Applicants' application pertains, the Examiner must rely only on analogous

prior art. See M.P.E.P. § 2141.01(a). The Federal Circuit has held that "analogous art" is art to which a person of ordinary skill, seeking to solve the problem addressed by the subject application, "would be expected or motivated to look." In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992). As applied to the present technology, analogous art is therefore art to which one skilled in the art of food science, seeking to solve the problem of fortifying bread with calcium, would be expected or motivated to look. In contrast, Drummond is directed to the use of an acid-stabilized calcium carbonate slurry "as a filler in neutral or acid paper to improve the optical properties of the paper" [col. 1, lines 7-9].

Not only are these very disparate arts, but the technical problems to be solved are quite different as well. As explained in Applicants' application, calcium carbonate cannot be added directly to leavened dough in sufficiently large amounts to contribute significantly to the calcium value of bread because of the buffering activity of calcium carbonate which prevents the pH from falling to the level required for fermentation [pp. 3-4]. Applicants' invention overcomes this problem by providing dough additives comprising dispersions of particulate calcium carbonate in acidic aqueous environments having a relatively stable pH within the pH range required for the chemical processes in dough to occur. Thus, Applicants' invention is concerned with dough additives which do not interfere with the natural processes of dough fermentation and the like.

In contrast, Drummond is concerned with an entirely different problem. As explained in Drummond, "in acid papermaking and under certain conditions in neutral papermaking, a filler material that is stable and resistant to attack by acid under weakly acidic to acidic conditions is required" [col. 1, lines 20-23]. Accordingly, it is clear that Drummond is concerned with preventing degradation of particulate calcium salts during paper-making. These

problems are conceptually distinct, as Applicants' invention seeks to preserve the pH of the substrate to which the additive is added, whereas Drummond seeks to prevent decomposition of an additive in the acidic environment of the substrate. In fact, moderate decomposition of the particulate calcium carbonate is not particularly detrimental to the practice of Applicants' invention so long as the proper pH is maintained, because, as explained in the application, Applicants' seek to avoid precipitation of large (conventional) calcium carbonate particulates in the dough which may lead to a grainy texture and poor "mouthfeel" of the resulting bread product. See [pp. 4, 10-11 and 17].

In summary, there simply would have been no reason, at the time Applicants made their invention, for one skilled in the art of <u>baking and dough additives</u> to look to the <u>paper-making</u> art. Because Applicants do not believe Drummond is properly citable as prior art, the particulars of the Examiner's rejections have not been addressed, however, Applicants reserve the right to do so. In light of the foregoing arguments, Applicants' respectfully request withdrawal of the rejections over Drummond.

# U.S. Patent No. 5,108,761 ("Andon")

Claims 1-20 stand rejected under § 103 as obvious over U.S. Patent No. 5,108,761 ("Andon"). The Examiner states that Andon discloses "an acidic beverage containing calcium citrate maleate" and argues that the amounts of the ingredients are within the claimed ranges. Applicant respectfully disagrees with this rejection for several reasons.

First, independent claims 1 and 12 require a specific weight ratio of calcium citrate to acid, namely, "about 4:1 to about 7:1." Contrary to the Examiner's assertion, Andon does not disclose compositions having a ratio of calcium carbonate to acid within the claimed ranges. The ratios of calcium carbonate to acid disclosed in Andon are <u>molar</u> ratios rather than

weight ratios. When converted to weight ratios, it is clear that the compositions of Andon have very different amounts of calcium carbonate and acid than those of the present claims. For instance, Example 1 of Anston discloses a composition having 200 g of calcium carbonate, 192 g of citric acid, and 201 g of malic acid. This represents a weight ratio of calcium carbonate to acid of approximately 1:2. Therefore, Andon does not fairly teach or suggest Applicants' claimed ratios of calcium carbonate to acid.

Additionally, independent claims 1 and 12 require acidic conditions. The compositions described in Andon are said to be non-acidic. For example, Andon states that "[c]alcium chloride, calcium phosphate and calcium sulphate are not suitable for use herein since the anions make an acidic solution, i.e., hydrochloric acid, sulfuric and phosphoric acid, respectively, which adversely affects the flavor of the calcium citrate malate." [col. 4, lines 13-17]. Andon therefore teaches away from Applicants' acidic suspensions of calcium carbonate.

Further, Andon teaches that when calcium carbonate is employed as the calcium salt, "it is necessary to mix until all of the calcium appears to have dissolved." [col. 4, lines 24-28]. Andon teaches that the "calcium citrate malate represents a soluble form of calcium." [col. 5, lines 18-20]. In contrast, independent claims 1 and 12 require a "calcium carbonate powder suspended in said aqueous solution of an inorganic or organic acid." Andon's disclosure of a soluble calcium salt in no way teaches or suggests Applicants' acidic dispersions of calcium carbonate powder but rather teaches away from this aspect of the present claims.

For at least the foregoing reasons, Applicants' submit that Andon has no relevance to the patentability of Applicants' claims.

#### U.S. Patent No. 5,260,082 ("delValle")

Claims 21-47 stand rejected under § 103 as obvious over Andon in view of U.S. Patent No. 5,260,082 ("delValle").

With respect to independent method claim 21 directed to a method of fortifying dough with calcium, the Examiner argues that delValle discloses "that it is known to incorporate a slurry of calcium citrate into baked doughs" and therefore it would have been obvious to incorporate a modification of the Andon and delValle compositions into dough. Further, the Examiner argues that independent method claim 42, directed to a method of fortifying a hamburger bun with calcium, would have been obvious over delValle's disclosure of bread products.

The combination of Andon and delValle does not render independent method claims 21 and 42 obvious because the references do not, alone or in combination, teach or suggest every element of independent method claims 21 and 42, and there is no motivation to combine Andon and DelValle in the manner suggested by the Examiner.

As discussed above, Andon discloses a specific water-soluble calcium citrate malate salt as an additive to beverages. Andon does not disclose additive compositions having: (1) "calcium carbonate powder suspended in said aqueous solution of an inorganic or organic acid," (Andon describes the <u>water-soluble</u> salt calcium citrate malate); (2) that "the weight ratio of calcium carbonate to acid is from about 4:1 to about 7:1," (Andon's compositions have a weight ratio of calcium carbonate to acid of approximately 1:2); and (3) that "the pH of the aqueous solution is about 3 to about 6.5" (Andon teaches that acidic additive compositions are not suitable).

DelValle does not rectify the deficiencies of Andon. DelValle discloses the reaction product of a calcium salt, such as calcium carbonate, with citric acid. [col. 2, lines 28-31]. As explained in delValle, the product is prepared by "neutralizing citric acid with a slurry of calcium carbonate." [col. 2, lines 41-47]. The reaction product (i.e., calcium citrate) is isolated by spray drying. [col. 2, lines 41-42]. The actual dough additive of delValle is a solid, crystalline form of calcium citrate [col. 2, line 41 – col. 4, line 28]. This is very different from Applicants' claimed invention which requires "calcium carbonate powder suspended in said aqueous solution of an inorganic or organic acid," rather than the reaction product which results under the specific conditions described in delValle.

Further, delValle does not disclose compositions wherein "the weight ratio of calcium carbonate to acid is from about 4:1 to about 7:1" DelValle discloses the ratios of calcium salt to citric acid as molar ratios rather than weight ratios. However, it is clear that delValle uses ratios of calcium to acid which are very different from the claimed weight ratios. For example, delValle Example 1 discloses the reaction product of calcium hydroxide and citric acid in a molar ratio of 2.29:2. In the case of calcium carbonate, this molar ratio would correspond to a weight ratio of calcium carbonate to acid of about 1:1.83.1

Finally, it will be noted that neither Andon nor delValle disclose additives comprising calcium carbonate powders. Andon teaches a calcium citrate malate additive and delValle teaches a calcium citrate additive. These are specific calcium salts which are not the same as aqueous suspensions of calcium carbonate powder as required by Applicants' claims.

<sup>&</sup>lt;sup>1</sup> Calcium carbonate has a molecular weight of 100.09 g/mol and citric acid has a molecular weight of 210.14 g/mol. Thus 2.29 moles of calcium carbonate weighs 229.2 g and 2 moles of citric acid weight 420.29 g, yielding a weight ratio of 1:1.83.

Thus, the combination of Andon and delValle is not sufficient to render the claims obvious because the references, either alone or in combination, do not teach or suggest every limitation of Applicants' claims.

Further, the skilled artisan would not have a reasonable expectation that the suggested combination would be successful. Applicants' direct the Examiner's attention to Example 2 of delValle which compares the pH of 1% aqueous slurries of delValle's spray-dried calcium citrate additive with slurries prepared from commercially available calcium citrate salt. DelValle's calcium citrate is shown to provide a pH from 3.95 to 7.28 (acidic to neutral), depending on the molar concentration of calcium and citrate, whereas commercially available calcium citrate yielded a pH of 9-11 (basic). The unique properties of delValle's calcium citrate additives are said to be "attributable to the particle size of the salt crystals, relying almost completely on the shape, number and geometrical arrangement of the calcium citrate crystals as they disperse in the water phase of the new food compositions of the invention." [col. 4, lines 21-28]. Thus, the skilled artisan would understand the compositions of delValle to be limited to a very specific method of preparation and would not reasonably expect that modification of delValle's compositions would preserve their ability to provide acidic slurries.

Finally, there is no motivation to combine the teachings of Andon and delValle. First, the additives of Andon (calcium citrate malate) and delValle (crystalline calcium citrate) are very different compositions. The calcium citrate malate of Andon is a water soluble calcium salt as an additive for beverages whereas the calcium citrate of delValle is a water insoluble calcium salt for addition to baked goods. Further, the additives of delValle are said to produce acidic slurries in water (Table I) whereas Andon teaches that acidic additives are to be avoided.

One skilled in the art would therefore not look to this combination because the additives are very different in composition, properties, and intended use.

The Examiner has not specifically addressed independent claim 36, but rejects claims 38 and 39, dependent from claim 36, as obvious over delValle. The Examiner states that DelValle discloses a baked bagel product . . . containing elemental calcium in the claimed amount with a pH of from 3.5 to 6." The Examiner states that "even though the pH in a baked product is not shown, it would have been close to the claimed pH when all the other ingredients were added as the calcium citrate slurry would have lowered the pH of the composition." Applicants' disagree with the Examiner's position because delValle is completely silent regarding the pH of any baked product. Further, as discussed above, delValle does not disclose adding a "calcium citrate slurry" to dough, as the Examiner suggests, but rather adds a solid crystalline calcium citrate to the dough. There is no basis for the Examiner's assertion that delValle discloses baked products having a pH "from about 3.0 to about 6.5" as recited in claim 36.

These disclosures are not sufficient to render obvious Applicants' claims because, among other reasons, the pH of the baked product is not specified in delValle. Nonetheless, solely to expedite prosecution of the application, claim 36 has been amended to require that the baked product "does not comprise spray-dried calcium citrate crystals." Support for this amendment is found at page 6 of the present application. Based on this amendment and the foregoing arguments, Applicants respectfully request withdrawal of the rejection of independent claim 36 over delValle.

In light of the foregoing amendments and remarks, Applicants respectfully request withdrawal of all rejections.

Applicants do not believe it is necessary at this time to further address the rejections of the dependent claims, as Applicants believe that the foregoing arguments and amendments place the independent claims in condition for allowance. Applicants reserves the right to further address those rejections in the future, if necessary.

## **CONCLUSION**

The Applicant respectfully submits that this application is in condition for allowance. If a telephone conference would facilitate prosecution of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

## <u>AUTHORIZATION</u>

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4517-4001. Furthermore, in the event that an extension of time is required, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-noted Deposit Account and Order No. 4517-4001. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

By:

Respectfully submitted, MORGAN & FINNEGAN, L.L.P.

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